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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,445	03/09/2001	Gary Van Nest	377882001300	7011

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PALO ALTO, CA 94304-1018

EXAMINER
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LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/802,445

Applicant(s)

NEST ET AL.

Examiner

Zachariah Lucas

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6, 9-12, 14 and 23-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 9-12, 14 and 23-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 March 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Currently, claims 1-4, 6, 9-12, 14, and 23-26 are pending in the application.
2. In the prior action, mailed on December 16, 2004, claims 1-4, 6, 9-12, 14, and 23-26 were pending and rejected. In the Response of March 15, 2005, the Applicant amended claims 1 and 9.

### ***Drawings***

3. **(Prior Objection –Maintained)** New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application for the reasons indicated in the Notice Of Draftperson's Patent Drawing Review, mailed with the action of January 2002, a copy of which is attached to the present action. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Applicant's attention is directed to 37 CFR 1.121 (d) stating the manner in which new drawings are to be submitted. In particular, it is noted that each sheet on which such new drawings are submitted must be marked as a "Replacement Sheet."

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **(Prior Rejection-Maintained)** Claims 1-4, 6, 23, and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These were rejected because it is unclear how the ISS can both delay the development of the lesion and be administered to the site of the lesion. The Applicant traverses the rejection on the basis that a delay in the development of such a lesion would be desirable, and that the phrase “delaying development” means to defer, hinder, slow, retard, stabilize, or postpone the development of the disease or symptom.

However, in the present case, the claim requires that the ISS be administered to the site of the lesion. It is unclear how the ISS can be administered to such a site without the lesion already being in place. Thus, the claims therefore exclude embodiments wherein the initial appearance of the lesion is deferred, slowed, retarded, or postponed.

Further, the doctrine of claim differentiation requires that the language of claims 1 and 9 include different subject matter. Claim 9 reads on methods of reducing the severity of the lesion. Since the administration of the ISS to the lesion could only defer, hinder, slow, retard, stabilize, or postpone the development of a lesion, thereby reducing its severity, it is not clear how claim 1 differs from claim 9 absent inclusion of the claim embodiments where the initial appearance of the lesion is delayed. However, as indicated above, because the ISS needs to be administered to the site of the lesion, such does not appear possible in the claimed method. The scope of what is being claimed in the methods of claims 1-4, 6, 23, and 24 is therefore unclear. The rejection is therefore maintained.

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6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. **(Prior Rejection- Withdrawn)** Claims 1-4, 6, 23, and 24 were rejected in the prior action under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of reducing the severity of a papillomavirus associated lesion when administered to the site of a lesion, does not reasonably provide enablement for methods of delaying the development of a symptom of a papillomavirus infection. In view of the amendment of the claims, limiting them to methods wherein the severity of the lesion is reduced, or where its development is delayed, the rejection is withdrawn.

8. **(Prior Rejection- Withdrawn)** Claims 1-4, 6, 9-12, 14, and 23-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims were rejected because, while the Applicant has demonstrated that the administration of an ISS may reduce the severity of a papillomavirus-associated lesion, the Applicant has not demonstrated that such treatment would have any effect on other symptoms of the viral infection. In view of the amendment of the claims, limiting them to methods wherein the severity of the lesion is reduced, or where its development is delayed, the rejection is withdrawn.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. **(Prior Rejection- Maintained)** Claims 1-4, 6, 9-12, 14, and 23-26 were rejected under 35 U.S.C. 103(a) as being unpatentable over Beutner, Bauman, and Yamamoto, and further in view of either of Raz et al. (U.S. patent 6,514,948), and Schwartz et al. (WO 98/55495- of record in the Feb 2002 IDS). The Applicant traverses this rejection on two grounds.

First, the Applicant argues that the teachings of Raz may not be combined with the teachings of Beutner and Bauman, as the methods of these teachings are not combinable. In particular, the Applicant notes that the teachings of Raz are concerned with the administration of the ISS prior to infection, whereas those of Beutner and Bauman administer the ISS after exposure. However, while the actual methods of the references may not be combined, the teachings of Raz with respect to the activity of the disclosed ISS molecules would clearly be relevant to those in the art familiar with the teachings of Beutner and Bauman. The teachings of all three references are concerned with the use of ISS molecules for the treatment of infections, and relate to the use of the same class of compounds. Thus, the teachings of these references all deal with the same art. While the methodology of Raz differs from that of the other references, this does not teach away from the use of the ISS of Raz in the methods of Beutner and Bauman. Rather, the common purposes and functions of the adjuvants used in these references indicate that they are functional equivalents, and that the ISS molecules of the Raz reference would be equally useful in the method of Beutner and Bauman. The Applicant's first argument in traversal is therefore not found persuasive.

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Second, the Applicant argues that the teachings of Schwartz do not provide support for a finding of a reasonable expectation of success because the reference “does not teach or suggest that administration of an ISS-containing polynucleotide without antigen results in the production of IFN- $\alpha$ .” This argument is not found persuasive. First, it is noted that the cytokine induction properties of the ISS is explicitly recognized in the Schwartz reference. See e.g., pages 4 and 29. These teachings, in addition to those of other references referred to in the prior actions, illustrate that those in the art would expected the ISS containing polynucleotides to induce IFN- $\alpha$  production in the absence of peptide antigens. The Applicant’s second argument is therefore not found persuasive.

For these reasons, the Applicant arguments that the combined teachings of the cited references fail to render the claimed methods obvious are not found persuasive. The rejection is therefore maintained for the reasons above and the reasons of record.

### ***Conclusion***

11. No claims are allowed.
12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

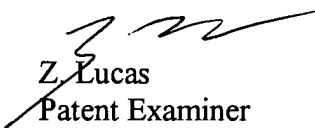
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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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4/4/05